REMARKS

Objection to the Specification and Claim Rejections Under 35 U.S.C. §112

The specification has been objected to under 35 U.S.C. §132 as allegedly introducing new matter into the disclosure. Specifically, the specification has been objected to as failing to support the following disclosure: "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of adjacent vertebral body". Additionally, claims 72-134 and 249-361 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, claims 72, 91, 111, 249 and 292 have been rejected in view of the recitation " . . . . less than approximately one-half of the width of the adjacent vertebral bodies . . . .", and it has been alleged that such recitation constitutes new matter.

In traversal of the objection to the specification and the rejection of claims 72-134 and 249-361 under 35 U.S.C. §112, first paragraph, the Applicant submits that the identified subject matter is fully supported by the original disclosure, including the as-filed specification and the as-filed drawing figures, and would be understood by a person of ordinary skill in the art to be clearly described in the specification and illustrated in the drawing figures.

The Applicant notes that MPEP §2125 states that, "the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art." (emphasis added) (citation omitted). The Office Action indicates that "applicant continues to argue the dimensions of the drawings and provides case law" and that "the MPEP states that the drawings are not to scale and one of ordinary skill in the art would not make the assumption of measurements". (Page 7, lines 5-9; emphasis added). However, the Applicant is not relying on "the dimensions of the drawings", nor is the Applicant relying on the "scale" of the drawings or "assumption of measurements". To the contrary, the Applicant is merely relying on what Figure 7 in the present application, in combination with the subject matter set forth in the specification, would reasonably convey to one of ordinary skill in the art. The Applicant is not relying on

or referring to any particular dimension, scale or measurement associated with Figure 7.

Each of the claims in the present application is directed to an "interbody spinal implant." The term "interbody" is understood by skilled artisans to mean located between the bodies of two adjacent vertebra. Paragraph 66 of the published version of the present application (Application Publication No. 2004/0073309) includes the following statement regarding the subject matter illustrated in Figure 6: "Bilateral placement of dowels 500 is preferred as shown in FIG. 6." The term "bilateral" is well understood by persons of ordinary skill in the art to mean located on two sides of a central axis. More specifically, in terms of interbody spinal implants, the term "bilateral" is understood to mean located on two sides of the central axis of the spinal column. Moreover, the dowels 500 depicted in Figure 6 do not overlap one another or cross the central axis of the vertebrae. Therefore, Figure 6, which depicts an embodiment of the invention involving bilateral placement of two dowels 500, would be clearly understood by a person of ordinary skill in the art to be characterized by each dowel having a width less than approximately one-half of the width of the adjacent vertebral body. This is the clearly the case irrespective of the dimension, scale or measurement of the dowels 500, or the size proportions between the vertebral bodies and the dowels 500. Accordingly, bilateral placement of two dowels 500 within the space between two adjacent vertebral bodies necessarily and inherently leads to the conclusion that the each of the dowels 500 must have a width that is less than approximately one-half of the width of the space between the adjacent vertebral bodies.

Moreover, additional disclosure in the specification also supports the claim language directed to implants having a "maximum width . . . less than approximately one-half of the width of the adjacent vertebral bodies . . . ." For example, paragraph 62 of the published application indicates that "[t]hese spacers are advantageous for maximum exposure of vertebral tissue to osteogenic material within the chamber and allow close placement of a pair of spacers within the intervertebral space." This statement teaches that the two spacers positioned "within the intervertebral space" do not overlap one another (i.e., they are simply placed in close proximity to one another). This teaching is also reinforced by the statement at paragraph 69 in the published application that "the [insertion] tool can be placed within the

channel during implantation, two spacers of this invention can be placed very closely together within the intervertebral space as shown in FIGS. 6 and 8." Furthermore, paragraph 67 of the published application would clearly convey to a person of ordinary skill in the art that the two spacers are positioned on opposite sides of the center of the intervertebral space via that statement that "two open spacers 500' can be implanted with the mouths 525' facing to the center of the intervertebral space."

Additionally, the Applicant again notes that the proper inquiry under Section 112, first paragraph, is whether the specification describes the identified subject matter, not whether alternative embodiments might exist that differ from an exemplary embodiment specifically shown and described in the specification and recited in a given claim. The Applicant submits that a person skilled in the art would have understood, based upon the drawings and the accompanying descriptions, that each of the embodiments depicted in Figures 6, 8 and 9 include two spacers that each have a width less than approximately one-half of the width of the adjacent vertebral body.

The Office Action refers the Applicant to MPEP §2125 and to the case of Hockerson-Halberstadt, Inc. v. Avia Group Int'l for the proposition that drawings can not be scaled to provide evidence of the actual size or dimensions associated with the features shown in the drawings. The Applicant generally agrees with this proposition. However, as indicated above, Figure 6 in the present application in not being scaled to determine the particular size or dimensions of the spinal implants 500, which was the issue specifically addressed in the Hockerson-Halberstadt decision. ("[I]t is well established that patent drawings . . . may not be relied on to show particular sizes if the specification is completely silent on the issue." 222 F.3d 951, 956 (Fed. Cir. 2000)). Instead, Figure 6 is being referred to in the context of illustrating the bilateral placement of a pair of spinal implants 500 in a side-by-side manner within the confines of the intervertebral disc space, and that such illustration would clearly convey to one of ordinary skill in the art that such bilateral placement necessarily dictates that the maximum width of each of the spinal implants 500 must be less than approximately one-half of the width of the adjacent vertebral bodies. The Applicant is not, however, relying

on Figure 6 to establish measurements which evidence the actual size or dimensions of the spinal implants 500.

Moreover, the Office Action also cites the decision of In re Wright for the proposition that drawing figures can be relied on "for what they would reasonably teach one of ordinary skill in the art." 569 F.2d 1124 (CCPA 1977). Indeed, this is precisely what the Applicant is relying on Figure 6 to convey. Specifically, Figure 6 clearly illustrates and paragraph 66 correspondingly describes the bilateral placement of a pair of spinal implants 500 within the confines of the intervertebral disc space, and such disclosure would reasonably convey to one of ordinary skill in the art that the maximum width of each of the spinal implants 500 must necessarily be less than approximately one-half the width of the adjacent vertebral bodies. Moreover, as set forth in MPEP §2163.06, "information contained in any one of the specification, claims, or drawings of the application as filed may be added to other part of the application without introducing new matter." (Emphasis added). Accordingly, the Applicant submits that it is proper to incorporate description into the specification based on information that the drawings would convey to one of ordinary skill in the art. As a result, the language added to the specification that each of the dowels 500 has a width less than approximately one-half of the width of the adjacent vertebral body (as shown in Figure 6) does not constitute new subject matter since the as-filed application clearly illustrates this feature of the claimed invention.

For at least the above-discussed reasons, the Applicant submits that the specification is properly supported by the present application as originally-filed. Accordingly, withdrawal of the objection to the specification under 35 U.S.C. §132 is respectfully requested. Additionally, the Applicant submits that claims 72-134 and 249-361 fully comply with the written description requirement, and therefore respectfully requests withdrawal of the rejection of claims 72-134 and 249-361 under 35 U.S.C. §112, first paragraph.

Claim Rejections Under 35 U.S.C. §102

Claims 72, 91, 111, 134, 249, 269 and 292 have been rejected under 35 U.S.C. 102(e) as being anticipated by Pafford et al. 6,371,988. It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior

art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

As an initial matter, the Applicant notes that claims 91, 111, 292 and 316 recite that the interbody spinal implant is made of "a bone composite material". However, the Office Action does not set forth any grounds whatsoever regarding the implant 10 of Pafford being formed of a bone composite material. Instead, the Office Action refers to Pafford as disclosing "[a]n interbody spinal implant (40) made of cortical bone". (Page 4, emphasis added). If the rejection of claims 91, 111, 292 and 316 is maintained, the Applicant respectfully requests an indication as to where in Pafford it is disclosed that the spinal implants are formed of materials other than cortical bone, and more specifically a bone composite material.

Additionally, the Office Action asserts that Pafford discloses that the implant 40 has opposed upper and lower portions that are non-arcuate along at least a portion of the length of the implant. The non-arcuate upper portion is asserted to constitute the beveled surface (shown in Figures 47 and 48) and the non-arcuate lower portion is asserted to constitute the crest 44 of the tooth 43 (shown in Figure 8). Albeit Pafford discloses that "the crest 44 of each tooth 43 is flat" (column 7, line 65), this description appears to be referring to the appearance of the crest 44 in axial cross-section (as shown in Figure 8) wherein the crest 44 may be considered "flat" in a circumferential sense (i.e., in that the crest 44 extending circumferentially about the implant does not have a pointed configuration as is typically the case with bone threads). However, such a "flat" crest 44 extending along the circumference of the implant would not be flattened along the length of the implant. In other words, when viewed from either end of the implant (or via a transverse cross section), the crest 44 would still have a circular or arcuate configuration. Accordingly, the "flat" crest 44 described in the '988 patent specification would not define upper and lower portions that are flat or non-arcuate along the length of the implant. If the claim rejections based on the assertion that the crest 44 of the tooth 43 is "flat" are maintained, the Applicant respectfully requests that specific grounds be set forth as to how an arcuate thread extending circumferentially about the implant 40 could be construed as "non-arcuate".

Moreover, the beveled surface shown in Figures 47 and 48 is referred to in the Office Action as comprising a non-arcuate upper portion. However, the Applicant respectfully disagrees with this assertion in that the beveled surface does not comprise an upper portion of the implant "to contact and support" an adjacent vertebral body, as recited in each of the rejected claims. Specifically, the opening or chamber 25 extending through the implant (as shown in Figures 7, 47 and 48) contains an osteogenic composition and opens onto the upper and lower surfaces of the implant to promote bone growth from the endplates of the respective vertebral bodies and into the chamber 25. (See column 7, lines 50-56). Thus, one or ordinary skill in the art would understand that when the implants are positioned in the disc space, the chamber 25 opens onto the upper and lower surfaces of the implant adjacent the respective vertebral bodies. As a result, the portions of the implant that define the openings of the chamber 25 correspond to the "upper and lower portions" of the implant, and do not correspond to the portion of the implant defining the beveled surface. Indeed, the beveled surface is positioned along lateral or side portions of the implant, which would correspond to the interior or exterior facing side of the implant recited in each of the rejected claims. Accordingly, even assuming that the beveled surface comprises a non-arcuate portion of the implant, the beveled surface does not comprise an upper or lower portion of the implant. Once again, if the claim rejections based on the assertion that the beveled surface shown in Figures 47 and 48 comprises a non-arcuate upper portion is maintained, the Applicant respectfully requests that specific grounds be set forth as to how the beveled surface comprises an upper or lower portion of the implant.

The Office Action further asserts that that recitation that "*said implant being manufactured from a bone ring obtained from a major long bone of a human having a modularly canal* are interpreted as Product by Process and are not limited to the manipulations of the recited steps." Even assuming arguendo that this assertion is accepted, the Office Action has not addressed several other structural features recited in the rejected claims. For example, claims 72, 134, 249 and 269 recite that when the implant is placed side by side with another implant which has "an interior side including at least a portion of a medullary canal a passage is formed", with the passage adapted to hold bone growth

promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is clearly illustrated in Figure 6 of the subject application wherein the interior facing sides 535 include at least a portion of the medullary canal so as to define facing chambers 530 of the bilaterally positioned implants 500 to form an elongated compartment 540 that can be filled with an osteogenic composition M. (See paragraph 66). The Applicant notes that the Office Action fails to set forth any grounds whatsoever as to how Pafford discloses these structural features.

As shown in Figure 24 of Pafford, although the implants are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants (i.e., the sides of the implants which face one another) clearly do not include at least a portion of a medullary canal, as recited in independent claims 72, 134, 249 and 269. Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants. Since the interior sides of the implants do not include "at least a portion of the medullary canal", Pafford does not disclose each and every feature recited in independent claims 72, 134, 249 and 269. Accordingly, Pafford does not anticipate independent claims 72, 134, 249 and 269. Moreover, the chambers 25 extending through the implants illustrated in Figure 24 of Pafford do not form a common passage that is adapted to hold bone growth promoting material. To the contrary, the chambers 25 form separate and discrete passages extending through the implants. Accordingly, for at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claims 72, 134, 249 and 269 as being anticipated by Pafford.

Additionally, independent claims 91, 111, 292 and 316 each recite that "said interior side of said implant including a recess so that when said implant is placed side by side with another implant having an interior side including a recess a passage is formed", with the passage adapted to hold bone growth promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is also clearly illustrated in Figure 6 of the subject application wherein the interior facing sides 535 of the implants 500 each include a recess, and with the opposing recesses forming a common

passage adapted to hold bone growth promoting. The Applicant notes that the Office Action fails to set forth any grounds whatsoever as to how Pafford discloses these structural features.

Although Pafford discloses implants that are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants do not include recesses which form a passage to hold bone growth promoting material, as recited in independent claims 91, 111, 292 and 316. Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants to form a recess. Since Pafford does not disclose each and every feature recited in independent claims 91, 111, 292 and 316, Pafford does not anticipate independent claims 91, 111, 292 and 316. Accordingly, for at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claims 91, 111, 292 and 316 as being anticipated by Pafford.

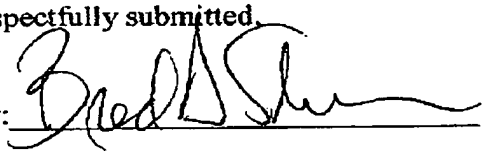
Moreover, claim 111 recites that "said leading end being asymmetrical from side to side", and claims 291 and 316 recite that "said leading end having a shape this is asymmetrical from side to side". However, Pafford does not appear to disclose such features. Additionally, the Office Action fails to set forth any grounds as to how Pafford satisfies these features.

For at least the reasons set forth above, the Applicant respectfully requests withdraw of the rejection of claims 72, 91, 111, 134, 249, 269 and 292 as being anticipated by Pafford, and an indication of allowability with regard to these claims is respectfully requested. The remaining claims depend either directly or indirectly from respective ones of the pending independent claims, and are submitted to be patentable for at least the reasons set forth above in support of their respective independent base claims.

CONCLUSION

In view of the foregoing remarks, the Applicant respectfully submits that each of the rejections asserted in the Office Action have been addressed and overcome. Accordingly, the Applicant respectfully requests entry of this response to the non-final Office Action and reconsideration of the present application including pending claims 72-135 and 249-361. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

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